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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,708	10/03/2003	Charlotte A. Kensil	8449-322-999	9606
20583	7590	01/11/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,708

Applicant(s)

KENSIL ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-65 is/are pending in the application.
- 4a) Of the above claim(s) 58-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-57 and 63-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment filed on 11/19/04 has been entered.

Claims 55-59 have been amended and rejoined for consideration.

Claims 46-65 are pending.

2. Applicants' election with traverse of Group I, claims 46-65 drawn to a method of enhancing an immune response with a composition comprising of antigen, saponin adjuvant and excipient, the elected species of a protein as an antigen and non-ionic surfactant as an excipient is acknowledged.

The restriction is traversed on the basis of MPEP 803.02, the subject matter of the individual species can be examined together in a single application without imposing a serious burden to the examiner. As art read on b-cyclodextrin differs from art read on human serum albumin and art read on lipid differs from art on polynucleotide, the species election is still deemed proper. Therefore, it is made FINAL.

Accordingly, claims 58-62 are withdrawn from further consideration by the examiner 37 CFR 1.142(b) as being drawn to a nonelected species.

Claims 46-57 and 63-65 drawn to a method for enhancing immune response with a composition comprising an antigen, wherein the antigen is a protein, saponin adjuvant, and an excipient, wherein the excipient is a non-ionic surfactant are under consideration in the instant application.

3. Applicants' claim for domestic priority under 35.U.S.C. 119 (e) is acknowledged.
4. Applicants' IDS filed on 10/3/03 is acknowledged.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1644

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46-57 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensil et al. (U.S. Pat. No. 5,057,540) in view of Allison et al. (U.S. Pat. No. 4,772,466).

As U.S. Pat. No. 5,057,540, which is incorporated by reference, acknowledges "QA" saponins are equivalent to "QS" saponins, QS saponins from the instant application will be examined as QA saponins from the reference.

Kensil et al. teach an immunogenic composition comprising an antigen, and saponin adjuvants (see col. 7 lines 32-64). They further teach the preferred antigen sources are bacteria, virus, and protein (i.e. gp 70), saponin adjuvants are QA-7, QA-17, QA-18, QA-21 or Quil-A (see cols 21-22, Example 14, claims 1-13), administration routes, an individual which can elicit immune response upon administering and concurrent administering of antigen and composition (see col 7, lines 6-7, 14-19, 65-68 and claims 15 and 16).

The claimed invention differs from the reference teachings only by the recitation of excipient, non-ionic surfactant.

However, Allison et al. teach vaccines comprising an antigen, and a polyoxypropylene-polyoxyethylene polymer for immunizing birds and mammals against viruses, bacteria, fungi or parasites. Allison et al. further teach non-ionic surfactants including polysorbate, polysorbate 20, polysorbate 80 (col 6, lines 46-48, in particular) and other sorbitan-based non-ionic surfactants are very useful in vaccine formulations as they increase efficacy of vaccine compositions, and stabilize the emulsion when suspension is formed (see cols 4-6).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ the excipient components taught by Allison et al. in the immunogenic composition to enhance the immune response taught by Kensil et al.

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One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the teachings of Allison et al. is an obvious way to increase efficacy and stabilize the vaccine formulation of the claimed invention. Thus, it is expected to combine teachings above to enhance the immune response and improve stabilization of vaccine formulation as in claimed invention.

From the combined teachings of references, one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

No claims are allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
December 29, 2004



Patrick J. Nolan, Ph.D.
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December 29, 2004